K083785

MAR 1 1 2009

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

CADI Scientific Pte. Ltd
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Contact Person: Mr. GOH Zenton, Ph.D.

Position/Title: CEO

Date of Preparation: February 23, 2008

(2) **Trade Name:** Cadi SmartSense Wireless Temperature Monitoring System

Common/Classification Name: Thermometer, electronic, clinical

Product Code(s): FLL; 21 CFR § 880.2910

Class: Class II

(3) **Predicate Device(s):** Substantial Equivalence to:

K Number	Model	Manufacturer
K033534	VitalSense Integrated Physiological Monitoring System	Mini Mitter Co., Inc. (now Respironics)
K003326	Funai Amy Mama Wireless Thermometer Monitor (Baby Minder)	Funai Radio & Communications Corp.

Reason for Submission: New device

(4) **Description of Device:**

The Cadi SmartSense Wireless Temperature Monitoring System is intended for wireless automated measurement of abdominal surface temperature in adults through neonates used in any instance where quantifiable measurement of temperature data is desirable.

The system further provides the SmartSense PC Application with a data-entry interface that allows users to manually enter other vital signs parameters.

The SmartSense PC Application additionally provides a Vital Signs Dashboard view for convenient viewing and monitoring of patients' monitored temperature and manually entered vital signs.

The Cadi SmartSense Wireless Temperature Monitoring System consists of the following proprietary components:

- ThermoSENSOR – patient applied wireless temperature sensor
- SmartNODE – wireless telemetry receiver – receives ThermoSENSOR data
- SmartSWITCH – sensor activator accessory
- SmartSense PC Application – PC application software

Additional system elements include information technology (IT) equipment used in a local area Ethernet network such as routers and switches.

(5) **Intended use:**

Abominal surface temperature monitoring provides a convenient means to track patient temperature and trends without limiting patient mobility. The system is intended to be deployed within a health care facility to allow the monitoring of temperature wherever the patient applied sensor is within range of a receiver or receivers.

Indications for Use:

The Cadi SmartSense Wireless Temperature Monitoring System is intended to measure abdominal surface temperature in adults through neonates. The ThermoSENSOR, a reusable temperature sensor, is applied to the patient by means of single use application tapes.

The ThermoSENSOR provides periodic wireless transmission of temperature data which is utilized by the SmartNODE wireless receiver and the SmartSense PC application program to record, store, and display the temperature information.

WARNING This equipment measures and reports abdominal surface temperature – where direct measurements of body core temperature are required, it is recommended to utilize appropriate core temperature monitoring devices for this purpose.

Prescription device.

(6) **Technological Characteristics:**

The CADI SmartSense Wireless Temperature Monitoring System employ the same technological characteristics as the predicate device to measure temperature – a thermistor temperature sensor changes electrical characteristics in response to temperature. The resultant electrical signal is digitized and transmitted to the host to determine the measured temperature. Temperature information is displayed on a PC monitor display.

The SmartSense system utilizes a four-layer architecture in which the temperature measurement and wireless transmit functions are managed by the ThermoSENSOR. Wireless receiver, SmartSWITCH accessory, and SmartSense PC application functions are managed by separate control programs.

(b) (1) **Non-Clinical Tests Submitted:**

The SmartSense System was evaluated to the requirements of the FDA guidance document on clinical electronic thermometers and referenced standards.

The system elements were tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, environmental operation and storage conditions, resistance to moisture ingress, and shock and vibration. The device passed all of the tests.

SmartSense PC/host software and embedded software in the subsystems was verified to requirements and validated to meet intended use by software and system level performance testing.

Sensor patient contact materials meet applicable standards for biocompatibility.

(2) **Clinical Tests Submitted:**

(none / none required).

(3) **Conclusions from Tests:**

As described above, the Cadi SmartSense Wireless Temperature Monitoring System including accessory ThermoSENSOR's function and perform in a manner equivalent to the predicate device(s) as validated by parameter and bench testing. Device safety is substantiated by compliance testing to applicable standards and by biocompatibility of patient contact materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

CADI Scientific Pte. Limited
C/o Mr. Stephen H. Gorski
Imagenix, Incorporated
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K083185
Trade/Device Name: CADI Scientific Pte.Ltd. Cadi SmartSense Wireless Temperature Monitoring System
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 23, 2009
Received: February 25, 2009

Dear Mr. Gorski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: CADI Scientific Pte. Ltd. Cadi SmartSense Wireless Temperature Monitoring System

Indications for use:

The Cadi SmartSense Wireless Temperature Monitoring System is intended to measure abdominal surface temperature in adults through neonates. The ThermoSENSOR, a reusable temperature sensor, is applied to the patient by means of single use application tapes.

The ThermoSENSOR provides periodic wireless transmission of temperature data which is utilized by the SmartNODE wireless receiver and the SmartSense PC application program to record, store, and display the temperature information.

Warning: This equipment measures and reports abdominal surface temperature – where direct measurements of body core temperature are required, it is recommended to utilize appropriate core temperature monitoring devices for this purpose.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083185